

DEC 21 2001

K013436

**510(k) SUMMARY**

**NormaTec, Inc.'s NormaTec PCD**

**Submitter's Name, Address, Telephone Number, Contact Person  
and Date Prepared**

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Contact Person: Jonathan S. Kahan

Date Prepared: October 16, 2001

**Name of Device and Name/Address of Sponsor**

NormaTec PCD

Laura Jacobs, M.D., Ph.D.  
60 W. Germantown Pike  
E. Norriton, PA 19401

**Common or Usual Name**

Noninvasive pneumatic compression device

**Classification Name**

Compressible Limb Sleeve

**Predicate Devices**

Camp GCS 2000 (K935998), Wright Linear Pump (K830577), Talley Multicom 500 (K915637), Mego Afek Lymphapress (K810338), and Baxter Pulsatile Anti-Embolism System Pump (PAS II) (K911853).

**Intended Use**

The NormaTec PCD is intended to be used to apply pressure to the extremities. The NormaTec PCD is indicated for use in the treatment of:

## **Lymphedema and other edematous conditions, including**

**Congenital lymphedema (Millroy's disease, lymphedema praecox, and lymphedema tarda)**

**Post-mastectomy lymphedema**

**Post-infection lymphedema**

**Post-traumatic lymphedema**

**Post-surgical lymphedema**

**Post-radiation-treatment lymphedema**

**Venous insufficiency**

**Venous stasis ulceration**

and the prevention of:

**Deep Vein Thrombosis**

## **Technological Characteristics and Substantial Equivalence**

The NormaTec PCD is substantially equivalent to its predicates because it has the same intended use and very similar technological characteristics. Both NormaTec's PCD and its predicates are intended to apply pressure to the extremities to treat edematous states like lymphedema, and to prevent deep vein thrombosis.

NormaTec's PCD has very similar components as its predicate devices and very similar principles of operation. Each device consists of an electrically generated source of compressed air, tubing to convey the pressurized air to the sleeve, control of pressure applied cyclically and simultaneous treatment of two limbs, if necessary. Like the predicates, pressure is pulsed to the affected limb for a specified period of time, followed by a rest period, according to the physician's prescription.

## **Performance Data**

The NormaTec PCD underwent electromagnetic interference testing, burst testing, safety testing and quality assurance testing. In all instances, the NormaTec PCD functioned as intended and the results observed were as expected.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 21 2001

Normatec  
c/o Mr. Jonathan S. Kahan, Esq.  
Hogan & Hartson, LLP  
555 Thirteenth Street  
Washington, DC 20004-1109

Re: K013436  
Trade Name: NormaTec PCD  
Regulation Number: 21 CFR 870.5800  
Regulation Name: Compressible limb sleeve  
Regulatory Class: II  
Product Code: JOW  
Dated: October 16, 2001  
Received: October 16, 2001

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

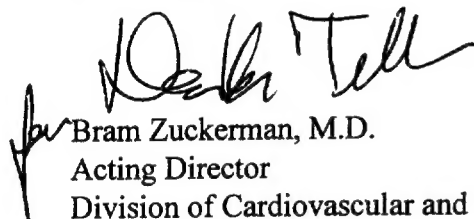
Page 2 - Mr. Jonathan S. Kahan

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram Zuckerman", is written over the typed name.

Bram Zuckerman, M.D.  
Acting Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE FORM

510(k) Number (if known): K013436

Device Name: NormaTec PCD

Indications for Use: The NormaTec PCD is intended to apply pressure to the extremities to treat:

**Lymphedema and other edematous conditions, including**

**Congenital lymphedema (Millroy's disease, lymphedema praecox, and lymphedema tarda)**

**Post-mastectomy lymphedema**

**Post-infection lymphedema**

**Post-traumatic lymphedema**

**Post-surgical lymphedema**

**Post-radiation-treatment lymphedema**

**Venous insufficiency**

**Venous stasis ulceration**

and to prevent:

**Deep Vein Thrombosis**

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K013436

Prescription Use X  
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use \_\_\_\_\_